Remarks

The office action identified several deficiencies with respect to the filing of the present divisional reissue application, and the claims have been rejected under 35 U.S.C. §§112 and 102. Claims 105-106, 108, 114 and 118-126 have been cancelled, and claims 104, 107, 109-113, 115-117, and 127-131 are pending in the application. Applicant herein submits its response.

Election/Restriction

The Office Action indicates that a constructive election has been made in the case, and that claims 120-125 have been withdrawn. Applicant has cancelled claims 120-125 by this amendment.

Claim Amendments

The claims previously presented have been amended in certain respects, as follows:

Amended Claim(s)	Amendment
104, 112, 113, 127, 129	Changed "edge" to "edge surface"
104	Referenced the channel as "having opposed sides" in line 6
104	Added last 5 lines referring to the opaque portions
109	Changed dependency from claim 108 to claim 107
115	Changed dependency from claim 114 to claim 113
128	Added "and between the opaque portions" in line 4
130	Added "and between the opaque portions" in lines 3-4
131	New claim

Assent of Assignee and Reissue Declaration(s)

Applicant herewith submits the Consent of the Assignee and a Statement Under 37 CFR 3.73(b). Applicant herewith submits also the declarations of inventors Surridge and McMinn. Applicant is obtaining the declaration for Crismore and will submit same in a supplemental response to the office action.

Reissue Oath/Declaration and §112 Support

Several claims have been rejected on the basis that support has not been indicated for these claims. Applicant herewith submits a claim table showing the support for the claims in the case.

The pending claims are clearly supported in the original specification of this application. These claims generally relate to electrochemical test strips which provide a means for the user to visually monitor the capillary flow of blood into the test strip. Further, the user is able to visually confirm that a sufficient amount of blood has been received in the test strip in order to conduct an accurate glucose test.

General support for the pending claims is found throughout the specification and the drawings. Attention is directed to the Abstract (lines 11-15), the Figures (particularly Figures 1, 3i and 5), and the disclosure found at column 1, line 61 to column 2, line 14; column 4, lines 1-48; and column 8, line 26 to column 9, line 9. In addition to these general portions of the specification, support for the claims can be found as follows:

Claims:	Support:
104. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:	Col. 5, lines 60-61: "In the preferred embodiment, test reagent 12 is formulated for the measurement of glucose in a human blood sample."
a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel having opposed sides extending from the sample application port to at least the vent;	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface;	Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent adjacent at least the working electrode; and	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test reagent 12 to . . . tracks 5 and 6."
visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary channel to accurately perform a test, said visualization means including a solid, transparent or translucent, viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,	See the figures, particularly FIGS. 1 and 3i. Abstract, lines 11-15: ". . . identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 36-36: "Further, insufficient sample may also be drawn into the capillary reaction chamber, thereby resulting in an inaccurate test result." Col. 1, line 60 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."

said visualization means further including said strip body having opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the viewing material and the opaque portions defining a viewing area required to be filled to have a minimum sample amount for said test strip.	Col. 8, lines 27-29: "A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
107. The test strip of claim 104 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes.	See Figures 3i and 5. Also see: Col. 8, lines 26-31: "The window is positioned and dimensioned so that when the roof is affixed to surface 8, it will align with opening 11 as shown in FIG. 3h." Col. 8, line 52 to col. 9, line 9: "Finally, roof 13 is placed onto surface 8. (See FIG. 3h) It is at this stage that the transparent or translucent window 18 defined by the absence of printed ink on roof 13 must align with opening 11 as shown in FIG. 3h."
109. The test strip of claim 107 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.	Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18.
110. The test strip of claim 109 in which the opaque portions are aligned with the opposed sides of the capillary channel.	See claims 107-109.
111. The test strip of claim 104 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
112. The test strip of claim 111 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a	See claim 104 and the Figures.

perimetric edge surface of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent, viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.	
113. The test strip of claim 111 in which the second substrate defines the opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes.	See claims 107-109.
115. The test strip of claim 113 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.	See claim 109.
116. The test strip of claim 115 in which the opaque portions are aligned with the opposed sides of the capillary channel.	See claims 106-109.
117. The test strip of claim 116 in which the opaque portions are defined by the roof.	Col. 8, lines 26-31: "Preferably, roof 13 is made of MELINEX 561 polyester foil, having a thickness of 5 mil. A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
127. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising: a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge surface, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent; at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge surface; a test reagent received within the test area of the capillary channel and adjacent at least the working electrode; said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at	See claim 104 and Figures 3i and 5.

or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area; said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test; wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.	
said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test; wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.	See claims 107-109 and the Figures.
128. The test strip of claim 127 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material and between the opaque portions in order to have a sufficient amount of blood sample to conduct a test.	See claim 104 and the Figures.
129. The test strip of claim 127 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge surface to the electrodes.	See claim 104 and the Figures.
130. The test strip of claim 129 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material and between the opaque portions in order to have a sufficient amount of blood sample to conduct a test.	See claim 104.
131. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising: a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel having opposed sides extending from the sample application port to at least the vent; at least working and counter electrodes spaced	See claim 104.

from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface; a test reagent adjacent at least the working electrode; and visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary channel to accurately perform a test, said visualization means including a solid, transparent or translucent, viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode, said visualization means further including said strip body having colored portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the viewing material and the colored portions defining a viewing area required to be filled to have a minimum sample amount for said test strip, the colored portions having a color which sufficiently contrasts with the color of the sample as viewed through the viewing material as to enable a user of reasonable visual acuity to determine if the viewing area is entirely full of the sample.	

Rejections Under §112

Claims 104-119 and 126-130 were rejected as being vague and indefinite as to the placement of the opaque portion. Claims 105-106, 108, 114, 118-119, and 126 have been cancelled and the rejection of those claims is thereby obviated.

Independent claim 104 has been amended to indicate that the opaque portions are "generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes" and that they define "a viewing area required to be filled to have a minimum sample amount for said test strip." This placement of the opaque portions is shown, for example, in FIGS. 1 and 3i. The capillary channel is defined on the opposed sides by the cutout or "second opening" 11 formed in substrate 7. By comparison, the top member 13 includes a transparent or translucent portion 18 which has opposed sides extending parallel to the sides of the channel. It is further apparent that the

strip therefore defines a viewing area which represents an area of the test strip required to be filled to have a minimum sample amount – i.e., the viewable area is an area of the capillary channel extending inwardly past the working electrode to the counter electrode. This is the area where a blood sample is required to be present for an electrochemical test to be conducted.

Claim 127 provides a strip body including opaque portions which define a "fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test." The claim further states that observation of the blood sample through the viewing material provides "confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test." This language is supported in the specification and the figures as indicated, for example, in the prior paragraph regarding claim 104.

New claim 131 includes a solid, transparent or translucent, viewing material," as well as "colored portions generally aligned with the opposed sides of the capillary channel . . . defining a viewing area required to be filled to have a minimum sample amount for said test strip . . . ." Again, this language is supported by the specification in the manner indicated for claim 104.

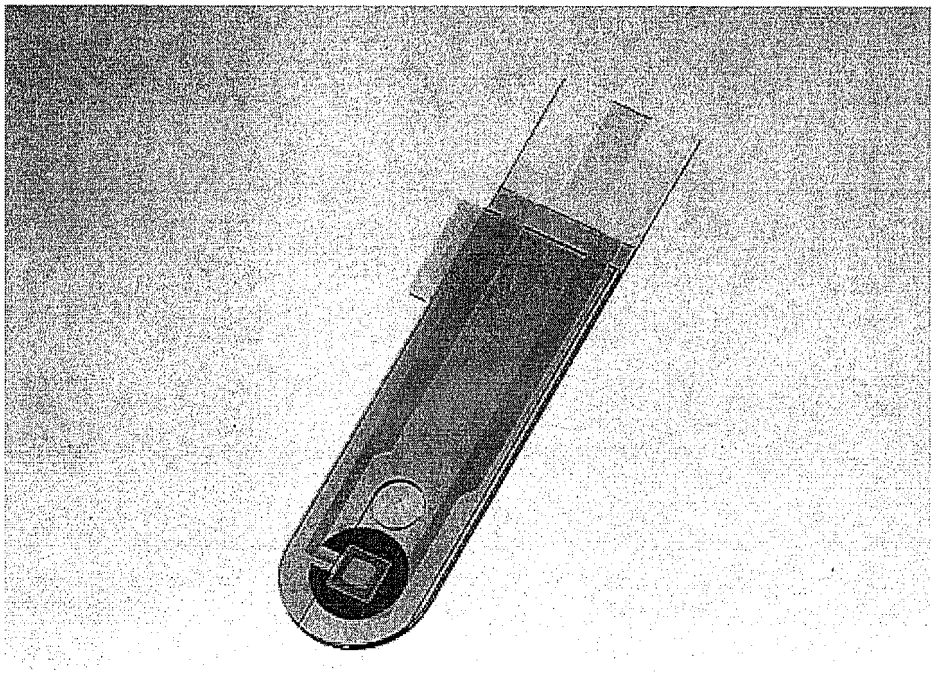
The import of each of the foregoing independent claims is straightforward. In general, the claimed inventions provide a test strip which – in contrast to the prior art – defines a viewing area as an area within opaque and/or colored portions which allow the user to see where the blood is filling, and to know that if the viewed area is filled then the test strip has been sufficiently dosed. This is in contrast to test strips which either provide no viewing of the blood sample as it moves through the capillary channel, or which do not limit viewing in a

manner that the user can readily watch the test strip fill with blood and know that there is sufficient sample. More specifically, this is in contrast to a test strip in which the entire upper layer is transparent and the user is not able to differentiate between the area of the test strip that needs to be filled with blood versus other areas of the test strip which do not need to be filled.

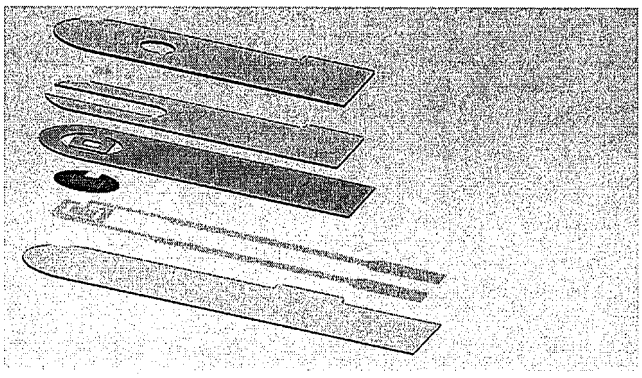
Rejections Under §102

As a preliminary comment, applicant notes that all of the devices described in the cited patent references are distinguishable from the present invention in the respect that they fail to disclose or suggest a capillary-fill, electrochemical test strip in which the movement of a blood sample to the electrodes and test reagent can be visualized to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area, such that the test results can be accurate. The cited art has not taught or suggested a configuration in which the area viewable by the user for a capillary-fill device distinguishes the area of the capillary channel up to the test area to be filled in order to sufficiently dose the electrodes and reagent of an electrochemical test strip, as opposed to other areas not needing to be filled.

In particular, the only rejection of the prior-pending claims was based on the prior art device known as Glucometer Elite, marketed by Bayer Corporation. On the following page is a picture of the Glucometer Elite product, showing the assembled device as marketed:



It is informative to consider the exploded view showing what are believed to be severn (7) distinct components of the strip:



The Glucomete Elite product is seen to comprise a number of layers, including (from top to bottom above) a top layer, reagent, spacer, dielectric layer (which shields portions of the electrodes from the capillary channel), carbon layer, electrodes and a base. However, there is nothing in the Glucometer Elite product which provides opaque and/or colored portions which

define a viewing area that indicates an area of the capillary channel which needs to be filled to conduct a test.

It appears clear that the top cover, spacer and dielectric layer are transparent or translucent materials, as the components underneath these layers are visible. For example, the carbon layer and the electrodes are located below the dielectric layer, and yet they are visible from the top in the assembled test strip. Similarly, the base appears to be a transparent or translucent material as the carbon layer and the electrodes are visible from the bottom of the test strip. Further, none of the top cover, spacer, dielectric layer or base includes any portions which are opaque, and to the extent the dielectric layer may be colored, it is uniformly colored throughout with no distinguishing portions which could identify the capillary channel. Therefore, none of the top cover, spacer, dielectric layer and/or base can provide the opaque and/or colored portions of the test strip as called for in the claims.

The carbon layer and the electrodes do appear to be opaque, and do provide colored portions which contrast with other areas of the test strip when viewed from the top or bottom. However, neither of these components provides portions which identify an area of the capillary channel needed to be filled in order to conduct a test. The carbon layer appears black in the test strip, and includes portions for the outer, circular electrode which lie outside the capillary channel. Therefore, a user who expected the carbon layer to be fully covered with blood would never see that occur, and could not use the opacity or coloring of the carbon layer as an indication that the capillary channel was sufficiently dosed.

Similarly, the electrodes can not provide such evidence for the user. As viewed from the top, the electrodes are hidden by the carbon layer and the reagent. As viewed from the bottom, the blood is hidden by the carbon layer. Consequently, the electrodes can not operate

to identify an area of the capillary channel that needs to be filled in order to conduct a proper test.

When blood is dosed to the Glucometer Elite strip, the user would be able to see blood moving into the strip, but would not be able to tell if it was filling the capillary channel or some lesser portion of the interior of the strip. When blood is dosed to a Glucometer Elite strip, the blood is viewable from the top, but it covers only about the middle half of the carbon layer. From the bottom, the presence of blood can be detected, but only in spaces between and outside the opaque electrodes.

In contrast, the present invention is directed to a test strip which includes opaque portions specifically located to enable the user to monitor whether sufficient dosing of the test area of the strip has been accomplished. This function is stated at various locations in the disclosure, including the following:

> "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip." Column 8, line 61 to column 9, line 9.

This feature is contained in all of the pending claims of this application. For example, claim 104 identifies "opaque portions defining a viewing area required to be filled to have a minimum sample amount for said test strip". Claim 127 requires "opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the

capillary channel needed to be filled to conduct an accurate test." New claim 131 includes "the viewing material and the colored portions defining a viewing area required to be filled to have a minimum sample amount for said test strip." These claim limitations distinguish the present invention from the Glucometer Elite test strip, which fails to provide opaque and/or colored portions which define a viewing area that confirms sufficient filling of the test strip when that viewing area has been filled with the blood sample.

The present invention is therefore seen to be uniquely distinguished from the above-described prior art. Reconsideration of the application and allowance of the pending claims are therefore respectfully requested.

Respectfully submitted,

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